REMARKS

Claims 1-12 remain under active prosecution in the present application. Claim 1 is presently amended. A Petition for Extension of Time for response is filed herewith.

By way of review, the present invention relates to a method by which biological materials may be detected in finished water. The method comprises the steps of obtaining a sample of finished water (that has been subjected to water treatment processes), wherein the finishing process modifies the biological agent of interest, followed by providing a recognition element such as an antibody or nucleic acid that has been altered such that the recognition element is able to bind to (recognize) the modified biological agent to be detected. The methods of the present invention allow one to detect biological agents that would otherwise resist detection by standard methods, due to chemical or molecular alterations resulting from the water treatment process.

In the subject Office Action dated November 30, 2006, the Examiner rejected all claims as failing to comply with the written description requirement as set forth by 35 U.S.C. §112. Further, the Examiner has maintained the rejection of obviousness under 35 U.S.C. §103 in view of Fritsch et al. (U.S. 2003/0108922) and Pyle et al. (U.S. 5,821,066). These rejections are addressed in detail below.

Claim Rejections - 35 USC § 112, First Paragraph

The Examiner has rejected claims 1-12 as failing to comply with the written description requirement under 35 U.S.C. § 112. This rejection was based on the language of claim 1 requiring "determining the effect the finished water has on the molecular recognition of the targeted agent by a molecular recognition element." The Examiner has rejected this language as not enabled, stating that the "determining" step is not effectively disclosed in the specification in such a way as to show one skille in the art how to accomplish this step.

In view of the Examiner's rejection, applicants have eliminated this language for clarity in amending claim 1 of the instant application. Applicants respectfully submit that the newly amended claim 1 is fully supported throughout the specification.

Claim 1 now requires the steps of 1) obtaining a sample of finished water suspected of having a targeted biological agent (support for which can be found, for example, in ¶0012), wherein the targeted biological agent has been altered by the effect of the finished water (support for which can be found, for example, in ¶0020); 2) providing at least one first molecular recognition element that is manipulated to recognize and specifically bind to the altered target reagent, wherein the alteration to the target reagent is a result of the natural qualities and/or additives present in finished water (support for which can be found, for example, in ¶0030); 3) flowing the sample over the first recognition element; 4) capturing the biological agent present in the sample by binding to the first recognition element (support for which can be found, for example, in the original Claim 1); and 5) detecting a signal indicating the presence of the targeted biological agent in the sample (support for which can be found, for example, in the original Claim 1).

Applicant respectfully asserts that amended claim 1 is fully enabled by the specification. That is, one of ordinary skill in the art is capable of obtaining a sample of finished water, and providing a modified recognition element to bind to an altered biological agent wherein the modified recognition element binds to the altered biological agent such that a signal is detected when the biological agent is present in the sample. In particular, the steps of "providing a modified recognition element" that binds to the altered biological agent is enabled at ¶0046.

For example, antibodies capable of binding to the altered targeted agent described in ¶0020 may be generated using standard methods of antibody production. These methods are well known in the art, and described at ¶0046. Further, identification of a suitable molecular recognition element (i.e., antibody) does not require that the alteration of the targeted agent is specifically identified. All that is required is that the altered agent can be recognized by the recognition element. As such, eliminating the determination step—which is not necessary to the practice of the instant invention as claimed—renders the instant claims fully enabled and in form for allowance.

Claim Rejections - 35 USC § 112, Second Paragraph

The Examiner has also rejected claims 1-12 as indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner has predicated this rejection on the method step of the previously submitted claims that required "determining the effect the finished water has on the molecular recognition of the targeted agent by a molecular recognition element." The Examiner asserts that this is vague and indefinite because it is unclear what the determining step encompasses. As set forth above, this portion of the method claims has been deleted as not essential to the operation of the instant invention. Rather, a molecular recognition element that recognizes and binds to a biological agent altered by the chemical milleu of finished water can be provided absent a "determining step" in which the precise molecular events are determined. In other words, the claims of the instant invention are fully enabled and distinctly claimed, in that one of ordinary skill in the art would readily appreciate the methods by which a molecular recognition element may be prepared, in view of the instant disclosure.

Claim Rejections - 35 USC § 103

The Examiner has rejected all pending claims under 35 U.S.C. § 103 as not patentable over Pyle et al (US 5,821,066) in view of Fritsch et al. (US 2003/0108922).

Applicants respectfully maintain that the prior art cannot be combined to teach all of the limitations of the pending claims, and the rejection under 35 U.S.C. § 103 cannot be sustained. The deficiencies of the prior art with respect to the presently amended claims are set forth in full below.

Claim 1 is presently amended to clarify, and place in proper form for allowance, the claim language of the instant application. As currently pending, the instant claims are directed towards a method of detecting biological agents in finished water, comprising the following steps:

- obtaining a sample of *finished water* suspected of having a targeted biological agent, *wherein the targeted biological agent has been altered by the effect of the finished water*;
- providing at least *one first molecular recognition element that is manipulated to recognize and specifically bind to the altered biological agent*, wherein the alteration to the targeted biological agent is a result of the natural qualities and/or additives present in finished water;
- flowing the sample over the first recognition element;
  capturing the biological agent present in the sample by binding to the first recognition element; and
- detecting a signal indicating the presence of the targeted biological agent in the sample.

Neither Fritsch nor Pyle discloses all of the above elements, as required to sustain a rejection under 35 U.S.C. § 102. In particular, though Fritsch discloses providing a first molecular recognition element that binds to a particular species of a microorganism, Fritsch *does not* disclose providing a first molecular recognition element that binds to a biological agent that is altered *due to the effects of a water finishing process*. Fritsch is solely concerned with, and the disclosure so limited to, determining the viability of species in a water sample, absent any finishing processes, wherein the first molecular recognition element specifically binds to a particular species. Thus, in Fritsch, the selection of an antibody (first molecular recognition element) is based on the biologically determined species of the target organism, not the effects of a water finishing process that molecularly alters the target agent.

The Pyle Reference Fails to Teach or Suggest a Step of Determining the Effect of Finished Water on the Molecular Recognition of the Targeted Agent, Followed by Selection of an Appropriate Molecular Recognition Element

To sustain a rejection under § 103, the combined prior art references must teach or suggest all of the claim limitations.

The amended claims now make clear that claim 1 also requires the step of selecting at least one molecular recognition element that specifically binds to the biological agent as determined by the effect of the finished water. This amendment now makes clear that the selection of a molecular recognition element is based on the alterations of the target agent due to the water finishing process. Pyle also fails to disclose this step.

Because the Fritsch reference is similarly deficient, as discussed below, that these references cannot be combined to form a valid basis for a rejection under 35 U.S.C. § 103.

The Fritsch Reference Also Fails to Teach or Suggest a Step of Determining the Effect Finished Water has on the Molecular Recognition of the Targeted Agent, or Selecting a Molecular Recognition Element that Binds to the Agent as Determined by the Effects of the Water, and Therefore Cannot be Combined with Pyle to Render the Present Invention Obvious.

The Examiner has argued that the present invention is obvious in view of Pyle et al. and Fritsch et al. However, as both references fail to disclose the same claim limitation, they cannot be combined to render the present invention obvious.

Fritsch et al. is directed towards a method of detecting waterborne pathogens, wherein pathogens such as bacteria are immobilized on a surface, followed by non-covalent attachment of electrolabeling molecules. The molecules are then activated so as to generate a current that may be measured and used to detect concentration of pathogens. While Fritsch et al. contemplates detection of pathogens in "drinking water," this reference does not disclose or suggest the step of determining changes in molecular binding properties of the target pathogen caused by treatment of the water. The Examiner, at page 3 of the Office action dated June 14, 2006, concedes that Fritsch et al. does not teach this step.

Similarly, Fritsch et al. does not teach the selection of a molecular recognition element based on alterations of the biological agent that results from the treatment process This reference is limited to disclosing a method of detecting pathogens and toxins in finished water without consideration of the effects of the water finishing process on the molecular recognition of the target agent. Because neither Fritsch et al. nor Pyle et al. disclose this limitation of the presently claimed invention, these references cannot be combined to render the present invention obvious. Applicants therefore respectfully submit that the rejection under 35 U.S.C. § 103 has been overcome and must be withdrawn.

CONCLUSION

In view of the above amendments and remarks, applicants respectfully submit that the objection to the claims under 35 U.S.C. § 103 have been overcome and must be withdrawn.

The claims as currently pending are now in condition for allowance. Accordingly, reconsideration and allowance of those claims, as amended herein, is earnestly solicited. Applicants encourage the Examiner to contact their representative, Stephen R. Albainy-Jenei at (513) 651-6839 or salbainyjenei@fbtlaw.com.

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

WILLIAM RICHARD HEINEMAN, et al.

By______________________________

Stephen R. Albainy-Jenei
Registration No. 41,487
Attorney for Applicant(s)
FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202
(513) 651-6823
salbainyjenei@fbtlaw.com